ABSTRACT

Study title:

A COMPARATIVE STUDY ON EFFICACY OF TOPICAL RECOMBINANT HUMAN EPIDERMAL GROWTH FACTOR (rhEGF) VERSUS EUSOL DRESSING IN THE HEALING OF DIABETIC WOUNDS

Background:

Diabetes mellitus comes under the group of metabolic diseases characterized by high blood sugar levels over a prolonged period due to alteration in either the insulin secretion, insulin action, or both. Worldwide, as of the recent 2016 data collected from the World Health Organization (WHO) around 422 million adults have diabetes mellitus. Diabetic foot, characterized by ischemia, peripheral neuropathy, osteoarthropathy, foot ulcer and infections possesses a major burden both to the community and to the patient. The lifetime risk of developing foot ulcers in diabetes is estimated to be around 15-20%. The amputation rates can be cut down to 49-85% by a multidisciplinary approach. With the latest advances in the theory, factors and cell types of wound healing, a new pathway has been initiated in the treatment of chronic diabetic foot ulcers. The present study was conducted to analyse the effectiveness of topical Recombinant Human Epidermal Growth Factor (rhEGF) in the healing of diabetic wounds as against the conventional EUSOL (Edinburgh University Solution of Lime) dressing. rhEGF cuts down the duration needed for wound healing and the mean closure was notably higher in the rhEGF group.

Objectives:

The aim of this study is to compare the efficacy of topical Recombinant Human Epidermal Growth Factor (rhEGF) versus EUSOL (Edinburgh University Solution of Lime) dressing in the healing of diabetic wounds in terms of:

- Duration required for wound healing.
- Rate of granulation tissue formation as percentage of the total surface area
- Rate of reduction in mean ulcer surface area.
- Any cellulitis in the surrounding area.

Primarily aiding in complete healing of the ulcer.

Secondarily resulting in the reduction of the surface area of the wound to get closed by suturing/skin graft/flap cover.

Methods and materials:

60 eligible patients who presented to Govt. Kilpauk Medical College and Hospital with diabetic foot ulcer are allocated into two groups with 30 patients in each group where group I receives the topical recombinant epidermal growth factor (rhEGF) dressing and group II receives the Edinburgh University Solution of Lime (EUSOL) dressing. The duration of the study is 5 months with a follow up period of 1 month. Patients with age <20 or >80 years, using steroids, chemotherapy or immunosuppressive drugs, with comorbid illness, wounds resulting from venous insufficiency/ malignancy/ischaemia , with evidence of osteomyelitis, septicaemia, wound sites other than lower limb, ulcers of grade III, IV and V and with doppler showing atherosclerotic changes and venous abnormalities like varicosities are excluded from the study.

Results:

In the present study, diabetic foot ulcer was most common in the age group between 61-70 years with 11 patients in the rhEGF group and 12 patients in the EUSOL group. There were 27 male patients (90%) in the rhEGF group and 22 male patients (73%) in the EUSOL group. The ulcers were more commonly located in the plantar aspect (73%). The patients were suffering from diabetes for a duration varying from months to years.24 (80%) patients in Group A were suffering from diabetes for duration of less than 5 years as compared to 12 (40%) patients in Group B. A total of 10 patients (33%) from Group A and 22 patients (73%) in Group B had surrounding cellulitis on admission. By the end of this study, one patient from Group A and 5 patients from Group B showed a surrounding cellulitis. On the 7^{th} day of treatment, patients in the study group had a mean granulation tissue of 37% over the wound as compared to 5% in the control group who received the EUSOL dressing. On day 14, 3 patients in the study group showed complete healing with a mean of 52% in the formation of granulation tissue while the patients in the control group showed 17% mean in the formation of granulation tissue. On day 21, out of the remaining 27 patients in the study group who received rhEGF, 5 patients showed complete healing and 2 patients underwent treatment for skin closure in the form of secondary suturing. A 66% mean in the formation of granulation tissue was noted in the rhEGF group as compared to 30% in the group of patients who received EUSOL dressing. 1 patient showed complete healing in the control group.

By the 28th day of the start of the treatment, 10 patients in the study group showed complete healing as compared to 1 in the control group. 3 patients in the control group underwent secondary suturing. The study group had a mean granulation tissue formation of about 72% as compared to 42% in the control group and there is a significant difference between the two groups with a P value of <0.0001 which is considered statistically significant. The mean size of the ulcer on admission was 3.85 sq.cm. in the study group and 3.92 sq.cm. in the control group which gradually reduced to 1.96 sq.cm in the study group and 3.31 sq.cm. in the control group as estimated on the 14th day of treatment. There is a definite reduction in the size of the ulcer in the study group which received topical recombinant human epidermal growth factor. 10 patients (33%) in the study group showed complete healing as compared to 1 (3%) in the control group. Healing by secondary intention was evident in 50% of the patients in the study group as compared to 43% in the control group. Ulcers were not healed in 2 patients (7%) in the group which received dressing with rhEGF as compared to 12 patients (40%) in the control group.

Conclusion:

Our study demonstrated the efficacy of topical recombinant human epidermal growth factor (rhEGF) in the healing of diabetic wounds in terms of rate of formation of granulation tissue and wound healing when compared with the control group who received EUSOL (Edinburgh University Solution Of Lime) dressing. Treatment with topical rhEGF can be added to the wide spectrum of treatment modalities available for the management of the diabetic foot ulcers after further research with a large population.

Keywords:

Diabetic foot ulcer, Recombinant human epidermal growth factor (rhEGF), Edinburgh University Solution of Lime (EUSOL)